REMARKS

Reconsideration of this application, is respectfully requested. The specification has been corrected. Claims 1-22 are pending.

Claims Objections

Claims 1, 5, 6, 11 and 12 stand objected to for recitation of non-elected inventions. Claims 1 and 4 upon which the objected to claims depend have been amended such that claims refer only to nucleic acids as required by the restriction requirement. Applicants therefore request withdrawal of these objections.

Rejection Under 35 U.S.C. 112, First Paragraph

Claims 1 and 3-22 stand rejected under 35 U.S.C. 112, first paragraph "because the specification, while being enabling for treating melanoma...does not reasonably provide enablement for treating any cancer...." Claim 3 has been cancelled with this amendment and the rejection thereof is accordingly moot. Claim 1, upon which claims 2 and 4-22 depend, has been amended to indicate that the type of cancer being treated is melanoma and that the type of cytokine being utilized is interferon.

The Examiner also referred to the phrase "high dose" of cytokine, alleging that this parameter "needs to be evaluated on a case-by-case basis for treating cancer via asserted enhanced T cell response." Claim 1 has been amended to require administration of a "therapeutically effective amount of interferon". As shown in Applicants' Examples 1 and 2 (see, in particular, paragraph [0083]), therapeutically effective amounts of IFN-α2b were found to range from the initial 20 megaunits (MU) down to approximately six megaunits depending upon the toxicity observed in each patient. As shown in the application, this may vary slightly depending on the particular patient being treated or interferon being utilized but selection of the effective dose is within the purview of the ordinary skilled artisan.

The Examiner also referred to the concept of "subsequent administration" as being "the novelty of the instant application." As shown in Applicants' Examples 1 and 2 (see, in particular, paragraph [0091]), IFN-α2b was administered to patients between 1.5 months and 17 months following their last administration of tumor antigen. These

"subsequent" times include 1.5, 3, 6, 7, 8 and 17 months (Table 1). Clinical regression was observed in patients treated with IFN-α2b 1.5 and 6 months subsequent to the last administration of antigen and the others showed no disease progression. The term "subsequently" directs the skilled artisan to that period of time during which administration of an interferon would be effective. The exact timing of the "subsequently administered" dose may vary between patients but selection of the effective time is within the purview of the ordinary skilled artisan.

For the reasons stated above, Applicants believe that the amended claims are enabled to their full scope. Applicants therefore request that these rejections be withdrawn.

Rejection Under 35 U.S.C. 112, Second Paragraph

Claims 1 and 3-22 stand rejected under 35 U.S.C. 112, second paragraph with respect to the phrase "high dose". The Examiner alleges that "[t]he specification fails to provide any specific guidance regarding how one skilled person in the art can extrapolate the amount of 'high dose or cytokine' from one specific cytokine to another cytokine." Claim 3 has been cancelled and the rejection as it pertains to claim 3 is therefore moot. Claim 1 (upon which claims 4-22 depend) has been amended to indicate that the cytokine is interferon administered in a therapeutically effective dose. As described above, Applicants' Examples 1 and 2 (see, in particular, paragraph [0083]) demonstrate that therapeutically effective amounts of IFN-α2b were found to range from the initial 20 megaunits (MU) down to approximately six megaunits depending upon the toxicity observed in each patient. This may vary depending on the particular patient being treated or interferon being utilized but selection of the effective dose is within the purview of the ordinary skilled artisan. Applicants believe that the meaning of a "therapeutically effective dose of interferon" would be understood by one of skill in the art from the instant specification and that the term is not unclear. Applicants therefore request that these rejections be withdrawn.

Rejection Under 35 U.S.C. 102(b)

Claims 1, 3-8 and 14-15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Paoletti (U.S. Pat. No. 5,942,235). Claim 3 has been cancelled and the rejection is therefore moot as to this claim. Applicants respectfully disagree and traverse this rejection as indicated below.

The Examiner alleges that Paoletti teaches "a cytokine secreted from modified tumor cells [that] can subsequently be utilized for active immunization". The Examiner also states that "administration of cytokine secreted by a tumor cell taught by Paoletti 1999 is distinct from co-expression of a tumor antigen and a cytokine from a viral vector." The Examiner's characterization of Paoletti's teachings is inconsistent with the cited disclosure. Paoletti clearly refers to the use of tumor cells modified to express "TAAs, cytokines, or other novel antigens" and states that "[s]uch modified tumor cells can be subsequently utilized for active immunization." (Paoletti, col. 16, lines 4-5). Paoletti does not teach isolation of the cytokine secreted from those modified cells and subsequent administration to a host, but administration of the modified tumor cells *per se*. In addition, Paoletti does not teach the use of therapeutically effective amounts of interferon as instantly claimed. Thus, Applicants believe this rejection is improper and therefore respectfully request its withdrawal.

CONCLUSIONS

Reconsideration of this application is respectfully requested. Applicants believe the claims are in condition for allowance and respectfully request the issuance of a Notice of Allowance as soon as possible. The Examiner is encouraged to contact the undersigned if it is believe doing so would expedite prosecution of this application.

Respectfully submitted,

Date: October 31, 2007

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